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SECTION 9 – 510(k) SUMMARY

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Allyson Barford Regulatory Affairs Associate DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-2794 Facsimile: 781-278-9578 e-mail: abarford@dpyus.jnj.com
Name of Medical Device	Device Regulation: Fastener, Fixation, Biodegradable, Soft Tissue (21 CFR 888.3030) Product code: 87 MAI Common/Usual Name: Biodegradable Fixation Fastener Proprietary Name: Spiralok Anchor
Device Classification	Suture Anchors are classified by the FDA as Class II Medical Devices. Absorbable PLA Suture Anchors carry a FDA product code 87 MAI, and are classified as Fastener, Fixation, Biodegradable, Soft Tissue under 21 CFR 888.3030.
Indications for Use	The Spiralok Anchor is intended for: Shoulder: Rotator cuff repair.
Device Description	The SpiraLok Anchor, like the current BioFastin RC Anchor, is a PLA threaded suture anchor preloaded on a disposable inserter assembly intended for fixation of two strands of suture to bone. Ethibond non-absorbable suture, the Panacryl absorbable suture and the Orthocord composite suture options may include tapered needles to facilitate suture passage through tissue. The attached suture is then used to reattach soft tissue back to bone where it reconnects through the healing

process.

Substantial Equivalence	The changes being made from the predicate BioFastin RC Anchor to the proposed Spiralok Anchor are either dimensional or material changes. The dimensional changes are minor (as described in detail in **Section 2** – Device Description) and do not affect the safety or effectiveness of the device. The second change is a material change to include a third suture option, composite Orthocord (K040004). Orthocord suture was previously cleared by FDA for use in general soft tissue approximation and/or ligation, including use in orthopedic surgeries. The addition of Orthocord suture option and the dimensional changes made to the design of the anchors do not alter the intended use, safety and effectiveness or the fundamental scientific technology of the predicate device. Mitek believes that the Spiralok Anchor is substantially equivalent to Mitek's BioFastin RC Anchor (K021883). A statement of substantial equivalence is provided in **Section 3** and the 510(k) "Substantial Equivalence" Decision-Making Process is attached in **Appendix III**.
Safety and Performance	The determination of substantial equivalence for this device was based on a detailed device description and changes that intend to be made to currently marketed devices. Non-clinical laboratory testing was performed demonstrating that the device is safe and performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Ruth C. Forstadt
Project Management Lead, Regulatory Affairs
Depuy Mitek
A Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K041069
Trade/Device Name: Spiralok Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: August 13, 2004
Received: August 16, 2004

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K041069

Device Name: Spiralok Anchor

The Spiralok Anchor is intended for:
Shoulder: Rotator cuff repair.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes (Per 21 CFR 801.109) OR Over-the-Counter Use No

for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices